# Exhibit A – Scope of Work

Project Summary & Scope of Work		
☐ Contract		

PI Name: Michelle D. Miller

**Project Title:** Agricultural Application Delivery Methods for Peptide Therapeutics

# **Project Summary/Abstract**

Innate Immunity LLC is nearing final commercialization of its novel HTH peptide therapeutic that is being tested/has been tested against a variety of gram-negative bacterial diseases in agricultural targets from grapes and citrus to apples and pears. Efficacy is strong and the peptide product is in later stages of development and product formulation. However, while we are confident that the peptide product (aka "the bullet") will both clear and inhibit persistent and existential bacterial diseases; the challenge facing commercialization is the application delivery methods (aka "the gun") that assures penetration of the plant by the peptide.

Innate has been working on this aspect to the problem for several years, using a variety of delivery methods in trials. But, there are pros and cons to each method, challenges to each target crops due to uniqueness of the plant target, and a realization that for the peptide to delivery most optimally and clear gram-negative diseases in plants, the application delivery method is the 'last mile' challenge to overcome. This grant proposal aims to solve this piece toward the delivery of a full circle solution (gun and bullet) to the enormous gram-negative disease profile inflicting global ag. This is the long-term goal of our proposal.

# **Scope of Work**

In field trials conducted over the past 3 years in citrus, grape and apple, the application delivery methods used (foliar spray, mechanized laser etching, trunk injection) has produced a variety of data that indicates both positive trends, as well as inconclusive data as it relates to various trial protocols. Complex and rigorous design protocols, followed by rigorous and detailed analysis of said trials, does not produce a clear 'winner' in the application delivery method. Different crop targets produce differing situations, challenges and farm management practice standards. For example, the waxy leaf in citrus presents significant application challenges; and this is why the laser etching method is under development by the citrus industry. Commonly used foliar spray is a likely application method to be used in some crops that can readily accept materials within a batch tank or is easily managed among other products. And truck injection, while able to assure penetration into the system of the plant/tree is ideal from a research standpoint, it is not a pragmatic solution long term for producers.

Additionally, the peptide itself has elements to it that may require a more sophisticated delivery method to optimize the performance and efficacy of the material in the plant. Therefore, we propose as part of this grant application your support to help facilitate the development of a nano carrier delivery method that will optimize the peptide's efficacy and penetration impact. Additionally, the work will continue to further test and evaluate the other application delivery methods.

Please find below pictures of the methods we are using in this project.

1. Laser Etching (proprietary technology under development of Premier Citrus Management Inc., Vero Beach, Florida.)





# 2. Foliar Spray



# 3. Trunk Injection



# **Project Objectives**

- 1. Design, test and finalize a nano carrier delivery method that is specifically designed to transport our peptide product into the plant material/system.
- 2. Trial and test the carrier method within the context of our current field trials to test against existing methods for efficacy, dosage, difficulty to manage, etc.
- 3. Determine a preferred method that will be included as part of the regulatory registration/label process

# **Exhibit A1 - Deliverables**

# **SCHEDULE OF DELIVERABLES**

Deliverable	Description	<b>Due Date</b>
Preliminary Design Specifications for nano carrier delivery method.	Objective 1a: among various design concepts developed by our team, and vetted by industry stakeholders, a selection of 1-2 nano carriers that meet our peptide's requirements, crop target requirements, and other relevant specifications; weaving in for consideration the potential regulatory paths may be impacted by various design features.	Months 1-5
	Objective 1b: <i>in silico</i> design of the nano materials.  Objective 1c: continue advancing 3 other delivery methods in 2022-2023 trials in apple, grape and citrus.	
Selection of high activity and specificity nano material carrier; Review and refinement.	Objective 2a: Continued testing of best performing nano carrier delivery method candidate <i>in vitro</i> . Objective 2b: End use formulation impacts of best performing candidate;	Months 5-9
Formulation process of nano method/peptide	Objective 3a: Formulation of a beta product that can meet regulatory, production and IP hurdles. Year One Status Report.	Months 5-12
Field trials	Objective 4a: Begin full field trials with new carrier method; test efficacy against other delivery methods.	Months 10-24
Refinement of product	Objective 5a: Continue refinement of product, testing against other delivery methods in active field trials across various crop targets.	Months 12-24
Project Conclusion Report	Objective 6a: Submit final report to Committee/State.	Month 24

# Exhibit A2 – Key Personnel

# **KEY PERSONNEL**

List Key Personnel as defined in the Agreement starting with the PI, by last name, first name followed by Co-PIs. Then list all other Key Personnel in alphabetical order by last name. For each individual listed include his/her name, institutional affiliation, and role on the proposed project. Use additional consecutively numbered pages as necessary.

Last Name, First Name	Institutional Affiliation	Role on Project	
PI:			
Michelle Miller	Innate Immunity LLC	Co-founder & Managing Member for Innate Immunity LLC. She will manage the grant and deliverables. She will oversee contributors to this grant; including designing studies, analyzing the results, and supervising the project personnel and all aspects of the project.	
Key Personnel:			
Aldwinkle, Herb, PhD	Innate Immunity LLC	Senior Scientist; Retired Cornell University; renowned authority on Erwinia Amylovora	
Browning, Harold, PhD	Premier Citrus Inc.	Senior Scientist; renowned authority on HLB/Citrus Greening; Leading development and testing of the laser etching method.	
Downs, Pete	Family Winemakers of California	Wine/grape consultant will facilitate choice of field trials locations and working with industry.	
Fowler, Jeff, PhD	Innate Immunity LLC	Senior Scientist; Retired Syngenta; Chemical Engineer; Product Formulation	
Pottathil, Ravi, PhD	Innate Immunity LLC	Senior Scientist; nano expert; will develop the technology of the nano delivery method	

# **RÉSUMÉ/BIOSKETCH**

Attach 2-3 page Resume/Biosketch for the PI and other Key Personnel listed in Exhibit A2, Key Personnel.

Our team represents various luminaries in ag-tech-science-disease. They bring both scientific and academic credibility, but also decades of active ag-tech commercialization and product development expertise. They also bring specific gramnegative bacterial disease knowledge and expertise.

#### Michelle D. Miller, MPA

Ms. Miller has 25+ years experience in commercialization of scientific discoveries, innovation and technology; product development; regulatory management; full team creation/management; executive management and operations; intellectual property development and management; go-to-market strategy, market development, strategic partnership creation, branding and public affairs.

She is Co-Founder and Managing Member for Innate Immunity LLC – a 6 year old ag-biotechnology startup focused on solving some of agriculture's most challenging diseases. As the executive officer for the company, she leads and oversees all scientific development for the company and product line; creates and oversees critical industry partnerships, raises equity investment, manages the board and investors, manages regulatory approval processes; and works with all stakeholders to develop and execute ROI for company. In this role, she leads the identification of promising discoveries that can set the stage for licensing, product development, co/joint strategic development with industry partners for purpose of solving existing market-based challenges, industry needs and other consumer and commercial opportunities.

Throughout her career, she has co-founded 20+ startups that have lead to successful product creation, ROI for investors and marketable products that have solved real-life problems and market needs.

- $\infty$  She has raised some \$100M in funding for commercialization efforts.
- ∞ Built and recruited the HD3 Advisory Network a global network comprising 1,500+ mentors, advisors, domain experts, investors, service providers, scientists, technologists, entrepreneurs, corporate/management professionals who lend their own expertise, guidance, connections to grow discoveries into marketable products.
- Launched "HD3 Discovery Day" that acts as a vetting panel to showcase early stage and other product concepts needing assistance to grow. Hosted 2-5 events per year for over a decade with some 1,000+ startup concepts, technology/scientific discoveries, have been presented, received feedback and evolved with HD3's assistance.
- ∞ Currently sits as a Board Director with 7 high value startup and young companies.
- ∞ Currently acts as an Advisor to numerous startup and young/maturing companies.

Throughout her career, Ms. Miller has held positions in all business sectors including the National Conference of State Legislatures, Association of Women's Health, Obstetrics and Neonatal Nurses, U.S. Small Business Administration, United States Senate, Tele-Communications, Inc. (TCI) and the Wall Street-based Chamberlain Communications. She is an entrepreneur who spots potentially successful concepts and discoveries and translates that into successful product development. She has been an original member of the board and management counsel to some 30+ startup ventures.

She graduated with Honors with a master's degree in Public Administration and Public Affairs from the University of Colorado in 1993. She also holds a bachelor of art degree from Colorado State University.

## Herb Aldwinkle, PhD

Emeritus Professor Section of Plant Pathology & Plant-Microbe Biology Cornell University Geneva, New York 14456

#### **Education:**

B.A.	Natural Sciences	Cambridge University, UK	1963
Ph.D.	Botany-Plant Virology	London University, UK	1967
Postdoc.	Plant Virology	University of California, Davis	1967-1968

#### **Professional Experience:**

Visiting Scholar		National Herbarium, Florence, Italy	1963 and 1966
Asst. Res. Plant Patholog	ist	Univ. of California, Davis/Berkeley	1967-1970
Asst, Assoc, Full Professo	or	Cornell Univ.	1970-2012
Emeritus Professor		Cornell Univ.	2012-present
Visiting Scientist		Cambridge Univ., UK	1977
Chair, Dept. of Plant Path	ology	Cornell Univ., Geneva	1982-1997
Visiting Scientist		Univ. of California, Berkeley	1986
Visiting Scientist		INRA, Angers, France	1987 and 1998
Visiting Scientist		IHD, Knoxfield, Victoria, Australia	2003

#### **Honors:**

Fellow, American Phytopathological Society, 1992

Distinguished Research Award, International Dwarf Fruit Tree Association, 2003
Lifetime Achievement Award, International Society of Horticultural Science, 2008
Career Accomplishments Award, College of Agriculture and Life Sciences, Cornell Univ., 2009
ISHS Recognition Award, ISHS International Workshop on Fire Blight. (2010)

# **Major Scientific Activities:**

Research and development of disease-resistant apple cultivars and rootstocks using plant breeding and biotechnology; apple structural and functional genomics; biology and control of fire blight; exploration for, characterization of, and evaluation for disease resistance of apple germplasm; coffee genomics.

#### **Synergistic Activities**

Developed efficient techniques for transforming apple cultivars, propagating transgenic plants and obtaining rapid flowering and fruiting, to allow early examination of transgenic genes, and shared the techniques with cooperators at Cornell and at institutions in the US and other countries, for disease resistance, insect resistance, delayed ripening, and floral development improvements.

Served on National Tree Fruit Technology Roadmap steering committee to identify research priorities, and to hold national workshops to discuss issues in research in general and in genomics.

Served as chair of the national Apple Crop Germplasm Committee and promoted the conservation of genetic resources of apple by participating in collection expeditions in central Asia, China and Turkey, and in evaluating germplasm for disease resistance genes.

Developed educational materials about genetically modified crops and foods, and made presentations to lay groups, including local legislators and community leaders, State legislators and their staff, and a NY State Senate hearing on a GMO moratorium.

Directed a 10-year training and research grant on biotechnology for improvement of coffee, and a current grant on coffee genomics at Cornell and other institutions in the US and France, sponsored by the National Coffee Growers Federation of Colombia.

## **Patents**

Inventor on 17 patents related to apples, 2 patents related to coffee, and 1 related to tomato.

#### **Consulting after retirement**

Served as consultant to companies on projects related to citrus transformation and resistance to HLB, to transgenic non-browning apples, and to novel treatments for control of fire blight of apple.

## **Advisor**

Served as advisor to university project in Kazakhstan to promote conservation of *Malus sieversii*, the wild apple of the Tian Shan (mountains) of Central Asia, in two trips to Kazakhstan in 2017 and 2019.

#### **Publications by Herb Aldwinckle**

#### **Refereed Journal Articles**

- **J.113** Fitch, M.M.M., Leong, T.C.W., He, X., McCafferty, H.R.K., Zhu, Y.J., Moore, P.H., Gonsalves, D., Aldwinckle, H.S. and Atkinson, H.J. 2011. Improved transformation of Anthurium. HortScience 46:358-364.
- **J.112** Wang, A., Aldwinckle, H., Forsline, P., Main, D., Fazio, G., Brown, S. and Xu, K. 2011. EST contig-based SSR linkage maps for Malus 3 domestica cv Royal Gala and an apple scab resistant accession of M. sieversii, the progenitor species of domestic apple. Molecular Breeding DOI 10.1007/s11032-011-9554-1.
- **J.114** Borejsza-Wysocka E, Norelli JL, Aldwinckle HS, and Malnoy M. 2010. Stable expression and phenotypic impact of attacin E transgene in orchard grown apple trees over a 12 year period. BMC Biotechnol. 2010 Jun 3;10:41.
- **J.111** Ko, K., Brown, S.K., Norelli, J.L., Hrazdina, G. and Aldwinckle, H.S. 2010. In vitro pollen functionality of attacintransgenic "Royal Gala" apple plants and apples transformed with 1-aminocyclopropane-1-carboxylic acid synthase (ACS)-antisense vector. Plant Biosystems 144:778-783.
- **J.110** Postman, J., Volk, G. and Aldwinckle, H. 2010. Standardized plant disease evaluations will enhance resistance gene discovery. HortScience 45:1317-1320.
- **J.108** Baldo, A, Norelli, J.L., Farrell, R.E.Jr., Bassett, C.L. Aldwinckle, H.S., and Malnoy, M. 2010. Identification of genes differentially expressed during infection with *Erwinia amylovora*. BMC Plant Biology 10:1.
- **J.109** Aldwinckle, H.S. and Malnoy, M. 2009. Plant regeneration and transformation in the Rosaceae. Transgenic Plant Journal 3 (Special Issue 1): 1-39.
- **J.107** Volk, G.M, Richards, C.M., Henk, A.D., Reilley, A.A., Reeves, P.A., Forsline, P.L. and Aldwinckle, H.S. 2009. Capturing the diversity of wild *Malus orientalis* from Georgia, Armenia, Russia and Turkey. J. Amer. Soc. Hort. Sci. 134:453-459.
- **J.106** Norelli, J.L, Lalli, D.A., Artlip, T.S., Boresjza-Wysocka, E., Malnoy, M., Bassett, C.L., Gidoni, D., Flaishman, M.A., and Aldwinckle, H.S. 200X. Estradiol-inducible gene expression in transgenic *Malus* (apple) via the XVE transactivator. Transgenic Research (submitted).
- **J.105** Malnoy, M., Boresjza-Wysocka, E.E., Norelli, J.L, Flaishman, M. A., Gidoni, D., and Aldwinckle, H.S. 2010 Genetic transformation of apple (*Malus X domestica*) without use of a selectable marker gene. Tree Genetics and Genomes 6:423-433.
- **J.104** Richards, C.M., Volk, G.M., Reeves, P.A., Reilley, A.A., Henk, A.D., Forsline, P.L. and Aldwinckle, H.S. 2009. Selection of Stratified Core Sets Representing Wild Apple (*Malus sieversii*). J. Amer. Soc. Hort. Sci. 134:228-235.
- J.103 Gasic, K., Gonzalez, D.O., Thimmapuram, J., Liu, L., Malnoy, M., Gong, G., Han, Y., Vodkin, L.O., Aldwinckle, H.S., Carroll, N.J., Orvis, K.S., Goldsbrough, P., Clifton, S., Pape, D., Fulton, L., Martin, J., Theising, B., Wisniewski, M.E., Fazio, G., Feltus, F.A., and Korban, S.S. 2009. Comparative analysis and functional annotation of a large expressed sequence tag collection of apple. The Plant Genome 2:23–38.
- **J.102** Sundin, G. W., Werner, N. A., Yoder, K. S., and Aldwinckle, H. S. 2009. Field evaluation of biological control of fire blight in the eastern United States. Plant Dis. 93:386-394.
- **J.101** Norelli, J.L., Farrell. R.E. Jr., Bassett, C.L., Baldo, A.M., Lalli, D.A., Aldwinckle, H.S. and Wisniewski, M.E. 2009. Rapid transcriptional response of apple to fire blight disease revealed by cDNA suppression subtractive hybridization analysis. Tree Genetics and Genomes 5:27-40.
- **J.100** Russo, N. L., Burr, T. J., Breth, D. I., and Aldwinckle, H. S. 2008. Isolation of streptomycin-resistant isolates of *Erwinia amylovora* in New York. Plant Dis. 92:714-718.
- J.99 Shulaev, V., Korban, S.S., Sosinski, B, Abbott, A.G., Aldwinckle, H.S., Folta, K.M., Iezzoni, A., Main, D., Arús, P., Dandekar, A.M., Lewers, K., Brown, S.K., Davis, T.M., Gardiner, S.E., Potter, D., and Veilleux, R.E. 2008. Multiple models for Rosaceae genomics. Plant Physiology 139:1313-1322.
- J.98 Volk, G.M, Richards, C.M., Reilley, A.A., Henk, A.D., Reeves, P.A., Forsline, P.L. and Aldwinckle, H.S. 2008. Genetic

- diversity and disease resistance of wild *Malus orientalis* from Turkey and southern Russia. J. Amer. Soc. Hort. Sci. 133:383-389
- **J.97** Malnoy, M., Xu, M., Borejsza-Wysocka, E., Korban, S.S. and Aldwinckle, H.S. 2008. Two receptor-like genes, Vfa1 and Vfa2, confer resistance to the fungal pathogen *Venturia inaequalis* inciting apple scab disease. MPMI 21:448-458.
- **J.96** Russo, N.L., Robinson, T.L., Fazio, G. and Aldwinckle, H.S. 2008. Fire blight resistance of Budagovsky 9 apple rootstock. Plant Disease 92:385-391.
- **J.95** Bulley, S.M., Malnoy, M., Atkinson, R.G., and Aldwinckle, H.S. 2008. Transformed Apples: Traits of Significance to Growers and Consumers. Transgenic Plant Journal 1:267-279.
- J.94 Malnoy, M., Jin, Q., Borejsza-Wysocka, E.E., He, S.Y., and Aldwinckle, H.S. 2007. Overexpression of the apple *MpNPR1* gene confers increased disease resistance in *Malus* × *domestica*. MPMI 20:1568-1580.
- J.93 Russo, N.L., T.L Robinson, G. Fazio, and Aldwinckle, H.S. 2007. Field evaluation of 64 apple rootstocks for orchard performance and fire blight resistance. HortScience 42: 1517-1525.
- **J.92** Borejzsa-Wysocka, E.E., M. Malnoy, W.-S. Kim, K. Geider, Beer, S.V., and Aldwinckle, H.S.. 2007. Expression of phi-Ea1h phage depolymerase gene with constitutive and inducible promoters, translation enhancer, and signal sequence in transgenic apple plants increases resistance to fire blight. Acta Hort. 738:273-276.
- **J.91** Borejzsa-Wysocka, E.E., Malnoy, M. Norelli, J.L., Beer, S.V., He, S., and Aldwinckle, H.S. 2007. Strategies for obtaining fire blight resistance in apple by rDNA technology. Acta Hort. 738:283-286.
- **J.90** Malnoy, M., Borejzsa-Wysocka, E.E., Abbott, P. Lewis, S. Norelli, J.L. Flaishman, M. Gidoni, D. and Aldwinckle, H.S.. 2007. Genetic transformation of apple without use of a selectable marker. Acta Hort. 738:319-322.
- **J.89** Malnoy, M., Borejzsa-Wysocka, E.E., Korban, S.S., and Aldwinckle, H.S. 2007. Role of *Vfa1*, *Vfa2*, and *Vfa4* genes in resistance to *Venturia inaequalis* in transgenic 'McIntosh' apple plants. Acta Hort. 738:323-328.
- **J.88** Norelli, J.L., Bassett, C. Artlip, T., Aldwinckle, H.S., Malnoy, M., Borejzsa-Wysocka, E.E., Gidoni, D., and Flaishman, M. 2007. Inducible promoters for use in apple. Acta Hort. 738:329-334.
- **J.87** Malnoy M., Reynoird J.P., Borejsza-Wysocka E.E., and Aldwinckle H.S., 2006. Activation of the pathogen-inducible *Gst1* promoter of potato after elicitation by *Venturia ineaqualis* and *Erwinia amylovora* in transgenic apple (*Malus X domestica.*). Transgenic Research. 15:83-93.
- **J.86** Volk G.M., Ann A. Reilley, Adam D. Henk, Christopher M. Richards, P.L. Forsline, and H.S. Aldwinckle. 2005. Ex situ conservation of vegetatively propagated species: Development of a seed-based core collection of *Malus sieversii*. J. Amer. Soc. Hort. Sci. 130:203-210.
- **J.85** Forsline, P.L. and H. S. Aldwinckle. 2004. Evaluation of Malus sieversii seedling populations for disease resistance and horticultural traits. Acta Hort. 663: 529-534.
- **J.84** Brown, S.K., K.E. Maloney, M. Hemmat and H.S. Aldwinckle. 2004. Apple breeding at Cornell: genetic studies of fruit quality, disease resistance and plant architecture Acta Hort. 663:693-697.
- **J.83** Norelli, J. L., Jones, A. L. and Aldwinckle, H. S. 2003. Fire blight management in the 21<sup>st</sup> century: using new technologies that enhance host resistance in apple. Plant Disease 88:756-765.
- **J.82** Norelli, J. L., Holleran, H. T., Johnson, W. C., Robinson, T. L., and Aldwinckle, H. S. 2003. Resistance of Geneva and other rootstocks to *Erwinia amylovora*. Plant Disease 87:26-32.
- **J.81** Aldwinckle, H.S., Malnoy, M., Brown, S.K., Norelli, J.L., Beer, S.V., Meng, X., He, S.Y., Jin, Q.L. and Borejsza-Wysocka, E.E. 2003. Development of Fire Blight Resistant Apple Cultivars by Genetic Engineering. Acta Horticulturae 622:105-111.
- **J.80** Hemmat, M., Brown, S.K., Weeden, N.F., Aldwinckle, H.S., and Mehlenbacher, S.A. 2003. Identification and mapping of markers for resistance to apple scab from 'Antonovka' and hansen's baccata #2. Acta Horticulturae 622:153-161.
- **J.79** Robinson, T.L., Aldwinckle, H.S., Fazio, G. and Holleran, T. 2003. The Geneva Series of Apple rootstocks from Cornell: Performance, Disease Resistance, and Commercialization. Acta Horticulturae 622:513-520.
- **J.78** Ko, K., Norelli, J. L., Aldwinckle, H. S., and Brown, S.K. 2002. T4 lysozyme and attacin genes enhance resistance of transgenic 'Galaxy' apples against *Erwinia amylovora*. Journal of American Society for Horticultural Science 127: 515-519.
- **J.77** Aldwinckle, H.S., Bhaskara Reddy, M.V., and Norelli, J.L. 2002. Evaluation of control of fire blight infection of apple blossom and shoots with SAR inducers, biological agents, a grow regulator, copper compounds, and other materials. Acta Horticulturae 590:325-331.

- **J.76** Aldwinckle, H.S., Gustafson, H.L., Forsline, P.L., and Bhaskara Reddy, M.V. 2002. Fire blight resistance of *Malus* species from Sichuan (China), Russian Caucasus, Turkey and Germany. Acta Horticulturae 590:369-375.
- **J.75** Breth, D.I., Aldwinckle, H.S., and Seem, R.C. 2002. Effects of weather conditions in development of "trauma" blight in apple shoots. Acta Horticulturae 590:143-145.
- **J.74** Breth, D.I., Aldwinckle, H.S. 2002. Comparison of models for blossom blight prediction in New York. Acta Horticulturae 590:147-151.
- **J.73** Forsline, P.L. and Aldwinckle, H.S. 2002. Natural occurrence of fire blight in USDA Apple Germplasm collection after 10 years of observation. Acta Horticulturae 590:351-357.
- **J.72** Norelli, J.L., Aldwinckle, H.S., Holleran, T.L., Robinson, T.L. and Johnson, W.C. 2002. Resistance of Geneva apple rootstocks to *Erwinia amylovora* when grown as potted plants and orchards trees. Acta Horticulturae 590:359-362.
- **J.71** Bolar, J.P., Norelli, J.L., Harman, G.E., Brown, S.K., and Aldwinckle, H.S. 2001. Synergistic activity of endochitinase and exochitinase from *Trichoderma atroviride* (*T. harzianum*) against the pathogenic fungus, *Venturia inaequalis*, in transgenic apple plants. Transgenic Research 10:533-543.
- **J.70** Bessho, H. Brown, S. K., Norelli, J. L., Aldwinckle, H. S., and Cummins, J. N. 2001. Observations on the susceptibility of Japanese apple cultivars and rootstock selections to fire blight. Journal of the American Pomological Society 55:120-124.
- **J.69** Luby, J., Forsline, P., Aldwinckle, H., Bus, V., and Geibel, M. 2001. Silk Road apples collection, evaluation, and utilization of *Malus sieversii* from Central Asia. HortScience 36:225-231.
- **J.68** Bolar, J.P., Norelli, J.L., Wong, K.-W., Hayes, C.K., Harman, G.E., and Aldwinckle, H.S. 2000. Expression of endochitinase from *Trichoderma harzianum* in transgenic apple increases resistance to apple scab and stunts growth. Phytopathology 90: 72-77.
- J.67 Ko, K., Norelli, J.L., Reynoird, J.P., Boresjza-Wysocka, E., Brown, S.K., and Aldwinckle, H.S. 2000. Effect of untranslated leader sequence of AMV RNA 4 and signal peptide of pathogenesis-related protein 1b on attacin gene expression, and resistance to fire blight in transgenic apple. Biotechnology Letters 22:373-381.
- **J.66** Lee, S. B., Ko, K. and Aldwinckle, H.S. 2000. Resistance of selected Malus germplasm to *Rosellinia necatrix*. Fruit Varieties J. 54:219-226.
- **J.65** Bolar, J.P., Brown, S.K., Norelli, J.L., and Aldwinckle, H.S. 1999. Factors affecting the transformation of 'Marshall McIntosh' apple by *Agrobacterium tumefaciens*. Plant Cell, Tissue and Organ Culture 54:55:31-38.
- **J.64** Reynoird J.P., Mourgues F., Aldwinckle H.S., Brisset M.N. & Chevreau E. 1999. First evidence for improved resistance to fireblight in transgenic pears expressing the attacin E gene from *Hyalophora cecropia*. Plant Science 149: 23-31.
- J.63 Ko, K., Norelli, J.L., Brown, S.K., and Aldwinckle, H.S. 1999. Anti-attacin polyclonal antibody from an in vitro derived antigen used for immunoblot to quantify attacin expressed in transgenic apple. Biotechnology Techniques 13:849-867.
- J.62 Ko, K., Brown, S.K., Norelli, J.L., and Aldwinckle, H.S. 1998. Alterations in *npt*Iland *gus* expression following micropropagation of transgenic M.7 apple rootstock lines. Journal American Society for Horticultural Science 123:11-18.
- **J.61** Momol, M.T., Norelli, J.L., Piccioni, D.E., Momol, E.A., Gustafson, H.L., Cummins, J.N., and Aldwinckle, H.S. 1998. Internal movement of *Erwinia amylovora* through symptomless apple scion tissues into the rootstock. Plant Disease 82:646-650.
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- **J.59** Hemmat, M., Weeden, N. F., Aldwinckle, H. S. and Brown, S. K. 1998. Molecular markers for the scab resistance (Vf) region in apple. Journal American Society for Horticultural Science 123:992-996.
- **J.58** Hokanson, S. C., McFerson, J. R., Forsline, P. L., Lamboy, W. F., Luby, J. J., Djangaliev, A. D., and Aldwinckle, H. S. 1997. Collecting and managing wild Malus germplasm in its center of diversity. HortScience 32:173-176.
- J.57 Momol, M. T., Momol, E. A., Lamboy, W. F., Norelli, J. L., Beer, S. V., and Aldwinckle, H. S. 1997. Characterization of Erwinia amylovora strains using random amplified polymorphic DNA fragments (RAPDs). J. Appl. Microbiol. 82: 389-398.
- **J.56** Norelli, J., Mills, J-A., and Aldwinckle, H. S. 1996. Leaf wounding increases efficiency of *Agrobacterium*-mediated transformation of apple. HortScience 31:1026-1027.

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#### **Patents**

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- **PAT.10** Aldwinckle, H.S. and Gaitan, A.L. 2005. Constitutive alpha-Tubulin promoter from coffee plants and uses thereof. U.S. Patent 6,903,247.
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#### Jeff Fowler, Ph.D.

INDUSTRIAL 30 years of hands-on, consultation and supervisory experience in formulation product development, formulation capability research, bioprocessing, modelling and data analysis. Led projects from basic research through to launch with aggregate peak sales over \$1b. A record of scientific breadth with patents and publications in diverse fields including adjuvancy, controlled release and RNAi. All employment below with Sandoz, Novartis and now Syngenta through the merger sequence.

- 2021: Innate Immunity LLC Project Leader Senior Scientist
- 2010-2020: Syngenta Fellow. Responsible for science strategy on formulation and delivery of RNAi, leader of a portfolio of projects focused on global formulation capabilities.
- 2002-2010: Research Scientist. Responsible for coordination of NAFTA formulation technology intellectual property projects. Member of team that sets global strategy on formulation technology innovation. Lead scientist on many new technology projects. Consultant on internal projects and external collaborations. Familiar with all conventional technologies in use in Ag formulations.
- 2001-2: Group Leader for NAFTA herbicide formulation development. Led a group of 9 with a portfolio of projects including the then biggest launch in our corporate history (Mesotrione mixtures with \$180 million first year sales).
- 1997-2001: Formulation Scientist, developed several commercial insecticide and fungicide products.
- 1996-7: Temporarily assigned to Basel, Switzerland to lead a research project on trans-cuticular uptake. Consulted on a Pseudomonad formulation project.
- 1995-6: Led small fermentation group working with biopesticide cultures from 1 to 20 liter scale. Participated in the first US scale-up of a recombinant biopesticide.
- 1989-96: Lead scientist responsible for biopesticide process development, formulation development and scale-up. Developed two products and participated in their successful launch, resulting in 50% increase in manufacturing capacity. Consulted on herbicide bioassay data analysis and some third-party technology collaborations. Invented a microencapsulated product with improved sunlight stability.

ACADEMIC Ph.D. in Chemical Engineering, Stanford University, January 1990 "Convective Transport in Immobilized Cell Aggregates". Advisor: Channing R.Robertson. Characterized morphology and hydraulic resistance of bacterial cell aggregates supported on porous membranes in a novel convective transport bioreactor. Demonstrated elimination of diffusional mass transfer limitations and proposed a mechanism for observed non-linear flow phenomena. M.S. in Chemical Engineering,

Washington University, December 1985 "Mixing and Nutrient Dispersal in Cultures of Saccharomyces cerevisiae". Advisor: Eric H.Dunlop. B.Eng. in Chemical Engineering, Imperial College, London University, June 1983. Coursework included approximately 1 year of business administration subjects. Teaching-Assistant (Stanford & Washington Universities) in biochemical engineering, fluid mechanics, process simulation & design, thermodynamicsAWARDS 2006 Syngenta Science Prize 1988 Sandoz Presidential Award 1979-83 National Engineering Scholarship, and sponsorship by ICI Organics Division

CONFERENCES ATTENDED & CONTINUING EDUCATION American Inst. Chemical Engineers, Annual National Conference 1989, 1990 (speaker), 1992, 1994, 1995, 1999, 2004, 2007, 2017 Royal Society Conference on Soft Interfacial Materials 2015 (session chair) IUPAC International Congress of Pesticide Chemistry 1994 (poster), 1998, 2014 (keynote speaker) Gordon Research Conference on Colloids & Soft Matter 2010 (session chair), 2012 ACS Colloid & Surface Science Symposium 2008 ICI / Akzo-Nobel Surfactants and Colloids Workshops 1996, 2003 Colloids, Polymers and Surfaces Program workshop, Carnegie Mellon University 2000 (speaker) ASTM 19th Symposium on Pesticide Formulation and Application Systems 1998 (speaker) Grid Management Techniques 1996 Managing Technology (AIChE short course) 1995 Entomological Society of America, Annual National Conference 1993 Brighton Crop Protection Conference 1992 Bt'91 Conference Oxford University 1991 Engineering Foundation Conference, Santa Barbara 1988 (speaker) Member American Institute of Chemical Engineers since 1984 PERSONAL Foreign languages: some French, German & Spanish Joint citizenship USA and UK

#### Ravi Pottathil, PhD, Innate Immunity Senior Scientist

OBJECTIVE Provide technical solutions to unmet market needs. WORK EXPERIENCE 1996-Present Chairman, Accudx Inc. San Diego, CA Responsibilities: ● Product development for diagnostic assays ● Consulting 2010-Present Managing Partner, IO-Mega, Keokuk IA Responsibilities: ● Product development for high value algal products 2011-Present Director, Nurture Earth, Aurangabad, India Responsibilities: • Product development for biofuel and algal technologies 2017-Present Founder/CTO, Naesscent LLC, San Diego, CA Responsibilities: ● Product development for diagnostic assays ● Consulting for business development 2004-2008 Vice President, XLTech Group Responsibilities: • Life Science technology evaluation and development • Business creation 1992-1996 Vice President, Specialty BioSystems, San Diego, CA Responsibilities: • Diagnostic product development • Manufacturing and marketing of diagnostic products in Asia and US 1985-1992 Section Manager, Hoffmann La Roche, Nutley, NJ Responsibilities: • Oncology and Infectious Disease section leader • Development of DNA probes, PCR, and automation products 1983-1985 Associate Professor, City of Hope Medical, Duarte CA Responsibilities: ● Down's syndrome, AIDS, and pediatric virology research 1980-1983 Assistant Professor, Pediatrics, Univ. Maryland Responsibilities: ● Research investigator in interferons, cancer, and virology EDUCATION 1978 - 1980 Postdoctoral Fellowship, Dr. Wolfgang Joklik, Microbiology & Immunology, Duke University Medical Center, NC 1975 -1977 Visiting Research Associate, Dr. Robert Huebner, The Jackson Laboratory, Bar Harbor, ME 1975 CTO, Zerogravity Solutions Inc, Boca Raton FL 2016-Present Doctorate, Applied Biology, Cancer Research Institute, Univ. of Bombay, India 1973 M.Sc., Applied Biology, Cancer Research Institute, Univ. of Bombay, India 1969 B.Sc., Zoology, Chemistry & Botany, Univ. Kerala, India Academic Appointments 2011-Present Adjunct Professor, Immunology & Nano-medicine, Florida International Univ., Miami, FL 2011-Present Science Advisory Board, School of Engineering, Florida Institute of Technology, Melbourne, FL 2009-Present Visiting Professor, Northwestern A&F Univ., Yangling, China 2008-Present Distinguished Professor, Marathwada College of Engineering, Aurangabad, India 1989-1992 Visiting Faculty, Rutgers Univ. Newark, NJ Career Highlights • Invented novel and universal method for biodiesel production from waste stream • Participated in the establishment of a number of state-of-the-art esoteric Clinical Reference Labs in Asia • Developed the first Point-of-Care diagnostic devices for HIV and dengue infection • Developed the first recombinant based HIV and HTLV-I and II blood screening assays • Participated in the team that developed the first commercial PCR assay and the first automated PCR instrument (Roche) • Elucidated the biochemical mechanism of interferon action and the role of oxidative enzymes in the establishment of an anti-viral state • Discovered the role of prostaglandin in the vascular complications of diabetic and lupus patients • Discovered small molecular weight RNA molecules (microRNA) present in embryonic and neoplastic cells with angiogenesis inhibitory activities Invited Speaker Presentations "Magnetic Nanoparticle-based Ablation of Cancer Cells in vitro and in vivo," Society for Personalized Nano-Medicine, Miami, FL. Nov. 1, 2018. Vaccines, Vaccination and Therapeutics, Organization Committee Member, Phoenix, AZ., Sept. 12-14, 2016. "Is the Decline in Honey Bees a Threat to Global Food Security", Panel Speaker, The World Food Prize, The Borlaug Dialogue International Symposium, Des Moines, IA., Oct. 15-17, 2014. "Nanotechnology: Current status and future trends in applied medicine", First Personalized Nanomedicine Symposium at FIU, Miami, Florida, Feb. 18, 2013. Nanotechnology: Current status and future trends in applied medicine", 4 th Annual NanoScience Technology Symposium at FIU, Miami, Florida, Sept 30, 2011. "Introduction to

Emerging Technologies and their application", Forefront Summit on Nanomedicine, Mumbai, India Dec. 12, 2011. "Peering into the Technologies of the Next Decade- Molecular Diagnostics - Current Status and Future Trends", IISC Conference, San Diego, CA. August 17-19, 2010. Publications/Patents 1. Pottathil R, Palayoor T, Batra BK. (1970). A non-Surgical method for intrauterine infusion of solutions in mice. India J. Exp. Biol., 9, 259-260. 2. Pottathil R, Batra BK, Menon IR. (1974). Specific in vivo stimulation of lymphocytes by tumor cell extract. India J. Med. Res., 62, 1025-1031. 3. Menon IR, Pottathil R, Batra BK.(1974). Specific rejection and regression of solid tumors by tumor cell extract. India J. Med. Res., 62, 1032-1038. 4. Pottathil R, Batra BK. (1974). Action of mitomycin C on preimplantation embryos. India J. Exp. Biol., 12, 487-489. 5. Batra BK, Pottathil R, Menon IR. (1975). Mechanisms of tumor regression by tumor extract. Indian J. Ed Res., 63(3), 1-35. 6. 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Transplacental teratogenic and carcinogenic effects in rabbits chronically treated with I -ethyl- I - nitrosourea. J. Natl. Cancer Inst., 56, 607-614 12. Pottathil R, Chandrabose K.A., Cuatracasas P, Lang DJ. (1980). Establishment of interferon mediated antiviral state: role of fatty-acid cyclooxygenase. Proc. Natl. Acad. Sci., 77, 5437-5440. 13. Pottathil R, Bedigian HG, Schultz L, Meier H. (1981). Biological and physicochemical properties of antitumor RNA. In: Niu and Chang, Eds. Proc. 2 d Intl. Symposium on RNA in Development and Reproduction. Beijing: Science Press, 546-580. 14. Chandrabose K.A., Cuatracasas P, Pottathil R, Land DJ. (1981). Interferon resistant cell line lacks fatty acid cyclooxygenase activity. Science, 212, 229-331. 15. Pottathil R, Chandrabose K.A., Cuatrecasas P, Lang DJ. (1981). Establishment of Interferon-mediated antiviral state: role of superoxide dismutase. Proc. Natl. Acad. Sci. USA, 78, 3343-3347. 16. Chandrabose K.A., Cuatrecasas P, Pottathil R.(1981). 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Pottathil R, Guittierez P, Davis HL, Chandrabose K.A.(1985). Growth of vesicular stomatitis virus in Hep-2 cells-role of membrane composition in virus penetration. J. Biol. Chem., 260, 5265-5270. 22. Lang DJ, Pottathil R, Pottathil IR. (1985). Cytomegalovirus infections after transfusion and transplantations: some studies of pathogenesis. 23. Forman SJ, Zaia JA, Pottathil R, et al. (1985). A 64,000 Dalton matrix protein of human cytomegalovirus induces in vitro immune responses similar to those of whole viral antigen. J. Immunol., 134, 3391-3395. 24. Pottathil R, Huang SW, Chandrabose K.A.(1985). Essential fatty acids in diabetes and systemic Lupus Erythromatus (SLE) patients. Biochem. Biophys. Res. Comm., 128, 803-808. 25. Pottathil R, Pottathil IR, Cheung KS, Lang DJ. (1986). Enhanced replication of murine cytomegalovirus in murine leukemic lymphocytes. Cancer Res., 46, 124-126. 26. Sloan NE, Lynn WR, Macleod RM, Hade EPK, Pottathil R, Kyriazis AP. (1986). 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## Harold Browning, PhD

Dr. Browning is ubiquitous in the US citrus industry and is widely known as a preeminent scientist in HLB, having spent his career at the Citrus Research and Development Foundation as Chief Executive Officer since 2011. He joined Premier Citrus in 2018 to lead efforts on commercializing a variety of HLB solutions as Chief Science Officer. In 2021, Dr. Browning joined Innate Immunity to lead citrus trials between Innate and all citrus producers nationwide, conducting sample analysis and trial data analysis. He will act as the point scientist to further the development of the HTH peptides that are showing promise to date; bring additional citrus stakeholders to the project; and advance progress in improving HLB-related challenges facing both FL and TX producers, but also anticipating HLB infections arising in CA in the coming years. Dr. Browning divides his time between Premier Citrus and Innate Immunity LLC. For many years, Dr. Browning has been involved in numerous NIFA projects, has sat on the NIFA review committees and leads Innate on related matters to achieve the NIFA grant requirements.

#### Edgar "Pete" Downs

Downs retired in 2012 from 20 years of service at Kendall-Jackson to launch his own consulting firm, and has been an active board member of Family Winemakers and head of the legislative committee. Jess Jackson, along with Bill McIver of Matanzas Creek, Patrick Campbell of Laurel Glen and Byrce Jones of Sonoma-Cutrer, founded Family Winemakers in 1990 to expand opportunities for smaller wineries to market wines directly to consumers, and fight for reasonable rules and regulations that allow family wineries to prosper and remain multi-generational operations. He guides Innate Immunity on grape/wine related industry relations, works to identify grape field trials with partners, interacts with Pierces Disease/CDFA Committee.

# **Exhibit A6 – Current & Pending Support**

Our team currently does not have current or pending financial support from any public entities at this time.

# Exhibit B - Budget

# **Budget for Project Period**

Principal Investigator (Last, First): Michelle D. Miller Exhibit B

COMPOSITE BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD 07/01/2022 to 06/30/2024

	From:	2022-2023	2023-2024		
BUDGET CATEGORY	То:	Voor 1	Voor 2	Voor 2	TOTAL
BUDGET CATEGORY		Year 1	Year 2	Year 3	IOIAL
PERSONNEL: Salary and fringe be	enefits.	\$20,000	\$20,000	\$0	\$40,000
TRAVEL		\$30,000	\$20,000	\$0	\$50,000
MATERIALS & SUPPLIES		\$25,000	\$25,000	\$0	\$50,000
TESTING		\$25,500	\$25,500	\$0	\$51,000
CONSULTANT		\$140,000	\$115,000	\$0	\$255,000
SUBRECIPIENT		\$0	\$0	\$0	\$0
OTHER DIRECT COSTS (ODC)	Subject to IDC Calc				
ODC #1	Υ	\$0	\$0	\$0	\$0
ODC #2	Υ	\$0	\$0	\$0	\$0
ODC #3	Υ	\$0	\$0	\$0	\$0
ODC #4	Y	\$0	\$0	\$0	\$0
ODC #5	Υ	\$0	\$0	\$0	\$0
ODC #6	Y	\$0	\$0	\$0	\$0
TOTAL DIRECT COSTS		\$240,500	\$205,500	\$0	\$255,000
Indirect (F&A)					
Costs	F&A Base		, .	, .	
<u>Rate</u>	MTDC *		\$0	\$0	\$0
			\$0	\$0	\$0
TOTAL COSTS PER YEAR		\$240,500	\$205,500	\$0	
TOTAL COSTS FOR PROPOSED PR	ROJECT PERIOD				\$446,000

<sup>\*</sup> MTDC = Modified Total Direct Cost

**JUSTIFICATION.** See Exhibit B1 - Follow the budget justification instructions.

Funds Reversion Dates: Unless otherwise specified as following, fund reversion dates are three years from fiscal year end of year funded

# Annual Budget Flexibility (lesser of % or Amount)

Prior approval required for budget changes between approved budget categories above the thresholds identified.

% 10.00%

Or

**Amount** \$10,000

Principal Investigator (Last, First):

Miller, Michelle

**Exhibit B** 

# **Anticipated Program Income**

# (applicable only when the funded portion of the project generates income) 10/01/2020 to 06/30/2021

From: To:	10/1/2020 6/30/2021			
	Year 1	Year 2	Year 3	TOTAL
ANTICIPATED PROGRAM INCOME	\$0	\$0	\$0	\$0

Anticipated Program Income is an estimate of gross income earned by the University that is directly generated by a supported activity and earned only as a result of the State funded project, and this fact is known by the University at time of proposal. Anticipated Program Income is an estimate of potential income and not a guarantee of income to support the project.

Page 2 of Exhibit B will only be incorporated in the Agreement when Program Income is anticipated and proposed.

Program Income is subject to Section 14.D of Exhibit C of this Agreement.

If known, provide source(s) of Program Income:

Source	Estimated Amount
N/A	

#### Exhibit B1

## **Budget Justification**

The Budget Justification will include the following items in this format.

#### Personnel

**Name.** Starting with the Principal Investigator list the names of all known personnel who will be involved on the project for each year of the proposed project period. Include all collaborating investigators, individuals in training, technical and support staff or include as "to be determined" (TBD).

**Role on Project.** For all personnel by name, position, function, and a percentage level of effort (as appropriate), including "to-be-determined" positions.

Michelle D. Miller (Principal Investigator), will be responsible for oversight of this project.

This project will be led by Michelle Miller (10% of \$200k annual FTE, Bio attached)

#### Fringe Benefits.

In accordance with University policy, explain the costs included in the budgeted fringe benefit percentages used, which could include tuition/fee remission for qualifying personnel to the extent that such costs are provided for by University policy, to estimate the fringe benefit expenses on Exhibit B.

#### Travel

Itemize all travel requests separately by trip and justify in Exhibit B1, in accordance with University travel guidelines. Provide the purpose, destination, travelers (name or position/role), and duration of each trip. Include detail on airfare, lodging and mileage expenses, if applicable. Should the application include a request for travel outside of the state of California, justify the need for those out-of-state trips separately and completely.

\$50,000 travel funds will include site visits for field studies, team meetings when needed and participation in the meetings requested to discuss project.

#### **Materials and Supplies**

Itemize materials supplies in separate categories. Include a complete justification of the project's need for these items. Theft sensitive equipment (under \$5,000) must be justified and tracked separately in accordance with State Contracting Manual Section 7.29.

\$25,000/year have been allocated for reagents, chemicals, enzymes, DNA/RNA sequencing, mass spectrometric analysis and other research development and in field needs.

# TESTING -

50k has been allocated for extensive testing by 3<sup>rd</sup> party of both lab and in the field trial data.

#### Equipment

List each item of equipment (greater than or equal to \$5,000 with a useful life of more than one year) with amount requested separately and justify each.

N/A

#### **Consultant Costs**

Consultants are individuals/organizations who provide expert advisory or other services for brief or limited periods and do not provide a percentage of effort to the project or program. Consultants are not involved in the scientific or technical direction of the project as a whole. Provide the names and organizational affiliations of all consultants. Describe the services to be performed, and include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

Herb Aldwinkle, PhD (10% of \$75k annual; consultant, CV attached)

Ravi Pottathil, PhD (25% of \$150k annual; consultant, CV attached), an expert in nano delivery methods. Will lead the technical development of a nano delivery method with the Innate Immunity peptide product.

Harold Browning, PhD (20% of \$150k annual consultant, Bio attached), leading commercialization of the laser etching delivery method on citrus trials.

Jeff Fowler, PhD (25% of 150k annual; consultant, CV attached) protein engineering and production, will participate in the chemical engineering elements related to the delivery methods in trial and formulation.

Pete Downs (25% 60k annual; consultant; Bio attached), will lead grape field trials to test various delivery methods under review/development on grape trials.

#### Subawardee (Consortium/Subrecipient) Costs

Each participating consortium organization must submit a separate detailed budget for every year in the project period in Exhibit B2 Subcontracts. Include a complete justification for the need for any subawardee listed in the application.

#### **Other Direct Costs**

Itemize any other expenses by category and cost. Specifically justify costs that may typically be treated as indirect costs. For example, if insurance, telecommunication, or IT costs are charged as a direct expense, explain reason and methodology. \$5,000 allocated to the publication cost and buying bioinformatic and modeling software.

#### Rent

If the Scope of Work will be performed in an off-campus facility rented from a third party for a specific project or projects, then rent may be charged as a direct expense to the award.

N/A

# Indirect (F&A) Costs

Indirect costs are calculated in accordance with the budgeted indirect cost rate in Exhibit B.